



## CERTIFICATE OF ANALYSIS

BioProfile FLEX Gas/Electrolyte Cal Cart  
Lot Number 19308020

Part Number 39543  
Exp Date 2021-02

Cal A L/N 19308020

	<u>Spec</u>	<u>Pass/Fail</u>
pH	7.381 - 7.387	Pass

Cal B L/N 19308020

	<u>Spec</u>	<u>Pass/Fail</u>
pH	6.837 - 6.843	Pass
iCa++ (mM)	1.97 - 2.03	Pass

Cal C L/N 19308020

	<u>Spec</u>	<u>Pass/Fail</u>
HCO <sub>3</sub> (mM)	19.6 - 20.4	Pass
NH <sub>4</sub> <sup>+</sup> (mM)	0.99 - 1.01	Pass
Na <sup>+</sup> (mM)	139.0 - 141.0	Pass
K <sup>+</sup> (mM)	3.97 - 4.03	Pass
iCa++ (mM)	0.99 - 1.02	Pass

Cal D L/N 19308020

	<u>Spec</u>	<u>Pass/Fail</u>
HCO <sub>3</sub> (mM)	39.2 - 40.8	Pass
NH <sub>4</sub> <sup>+</sup> (mM)	4.95 - 5.05	Pass
Na <sup>+</sup> (mM)	74.5 - 75.5	Pass
K <sup>+</sup> (mM)	9.92 - 10.08	Pass

Reference L/N 19308020

	<u>Spec</u>	<u>Pass/Fail</u>
KCl (M)	1.8 - 2.2	Pass

This certifies that this product was manufactured and tested at Nova Biomedical Corporation, Waltham MA 02453 U.S.A in accordance with ISO 13485:2016 Medical Devices Quality Management Systems Requirements, Medical Device Single Audit Program (MDSAP), and conforms to the indicated test specifications. The following analytes are traceable to NIST SRM Materials: Na, HCO<sub>3</sub>, pH, KCl, iCa, NH<sub>4</sub>, K.

Approval

QC Inspector  
Title

11/15/2019  
Date